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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,030	09/21/2001	Hideaki Yagi	Q66254	4266

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SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, NW
Washington, DC 20037-3213

EXAMINER
RADEMACHER, MARK A

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/957,030	YAGI ET AL.	
	Examiner	Art Unit	
	Mark Rademacher	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☒ Claim(s) *1 and 9-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The use of the trademark SIROOCO® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

3. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

4. The disclosure is objected to because the applicant has used sixth paragraph, means-plus-function language to define features of the applicants' invention. Accordingly, the examiner requires the applicants to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicants to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see MPEP 2181 (Rev. 1, Feb.2000)).

Appropriate correction is required.

Claim Objections

5. Claims 9, 10 and 11 are objected to for the following reasons. In each of the claims the applicants recite a flow rate that "represents" another flow rate. For example, in claim 9 the applicants recite "a continuous base flow rate, which represents a flow rate at which the oxygen enriching apparatus supplies the oxygen-enriched gas continuously. The nature of a flow rate that "represents" another flow rate is not clear form the specification, the claims or the prior art.

6. In order to increase the clarity of the claims the examiner suggests that the applicants correct the above clauses to read "a continuous base flow rate that is the flow rate at which the oxygen apparatus can supply oxygen-enriched gas continuously", or "which third flow rate that is the flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched gas continuously".

7. In addition, claim 1 is objected to because the applicants has evoked sixth paragraph, means-plus-function language to define features of the applicants' invention. Therefore the examiner objects to the claim for the reasons set forth above in the objection to the specification.

8. Also in claim 3 recites the applicants recite "the predetermined judgment condition is such that a period during which the state of breathing of the user cannot be accurately determined". In claim 4, the applicants also recite "a predetermined period". However, in base claim 1 the applicants had previously recited "a predetermined period when the state of breathing of the user cannot be accurately determined." It appears that the applicant is referring to the same "predetermined period" in each of the claims. Accordingly, the applicant should correct claims 3 and 4 so as to recite "the predetermined period", if accurate.

9. In addition to making corrections to address the above objections, the applicant is invited to review the claims and make similar corrections where appropriate.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 2, 6 and 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 4,681,099 to *Sato et al.*

12. *Sato et al* disclose a sensor for detecting the state of breathing of a user in the form of a thermocouple (28), judging means in the form of control unit (48), which translates signals from the sensor to judge the state of breathing based on a predetermined judgment condition, for example a set duration for normal inhalation and exhalation. See, e.g., column 12, lines 63-65. *Sato et al* further disclose supplying means in the form of breath synchronizing solenoid valve (24), oxygen concentrator (1) and associated conduit and cannulae (26). The supplying means disclosed by *Sato et al* act to continuously supply the oxygen-enriched gas to the user over a predetermined period when the state of breathing cannot be accurately determined over a predetermined period (e.g., the period during which predetermined normal breathing parameters are not detected) when the state of breathing cannot be accurately detected. See, e.g., column 12, line 63 through column 13, line 3.

13. With respect to claims 2, the oxygen supplying apparatus discussed in the context of the preferred embodiment comprises and oxygen enriching apparatus.

14. With respect to claim 6, the sensor (28) is mounted on the nasal cannulae (26), which is an oxygen outlet to the user.

15. With respect to claims 9-11, *Sato et al* disclose an apparatus that supplies gas continuously to a user at a flow rate less than or equal to a continuous base flow rate when breath synchronized operation is not performed. This occurs when the duration of inhalation or exhalation falls outside a predetermined duration range (see, e.g., the paragraph bridging columns 12 and 13) and during the initial start up of the apparatus (see, e.g., column 12, lines 41-46). *Sato et al* also discloses that when breath synchronized operation is performed, the oxygen enriching apparatus supplies the enriched gas during the inhalation cycle at a flow rate greater than the continuous base flow rate and stops the supply of gas (i.e., gas is delivered at a flow rate less than a continuous base flow rate) during the exhalation period. See, e.g., FIG 7B where the continuous base flow rate may correspond to the plateau region of the flow curve.

16. With respect to claims 12-14, *Sato et al* disclose examples in which the base flow rate of oxygen is less than 4 liters/min. See, e.g., TABLE 2 in column 14.

17. With respect to claims 15 and 16, Sato et al disclose a controller (48) for controlling the operation recited in claim 1 and a recording medium (memories 51-54) having recorded thereon means for executing the function of the controller.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 4,681,099 to *Sato et al.*

20. *Sato et al* disclose all of the features recited in claims 3-5 without expressly disclosing the specific duration of the time period during which the state of breathing of the user cannot be detected.

21. However, the selection of the particular predetermined period would have been obvious. The general rate of respiration and the duration of inspiration of a human were well known at the time of invention. Therefore, it would have been obvious to set the predetermined period to correspond to the lowest average breathing rate of a human as the applicant has done and further correspond to that portion of the inhalation cycle that corresponds to inhalation since this is the period during which the user takes in gas. Moreover, the applicant has not asserted that the specific predetermined periods recited provide a particular advantage, solve a particular problem, or serves a purpose different from that of any other period derived from the range of average human respiration.

22. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 4,681,099 to *Sato et al* in view of US patent no. 5,137,017 to *Salter*.

23. *Sato et al* disclose all of the features recited in claims 7 except that the sensor is disposed at a breath detection ort provided separately from an oxygen outlet.

24. However, such an arrangement was known at the time of invention. For example Salter discloses a demand oxygen system that includes a dual cannulae that is divided into two zones (4 and 5). Zone 4 and its associated nare (6), i.e., breath detection port, communicates with the

pressure-sensing unit (T). Zone 5 and its associated nare (7), i.e., oxygen outlet, delivers oxygen to the user. See, e.g., the paragraph bridging columns 1 and 2.

25. At the time of invention it would have been obvious to one with ordinary skill in the art to modify the apparatus disclosed by *Sato et al* to include the dual cannuala assembly disclosed by *Salter*. One would have been motivated to do so in order to prevent the oxygen delivery from influencing the parameter sensed by the sensor.

26. With respect to claim 8, *Sato et al* disclose all of the features recited except for the sensor being a pressure sensor, stain gauge sensor or a piezoelectric sensor. Instead, Sato et al discloses a thermocouple sensor to sense the breathing condition of the patient.

27. However, the other types of sensors recited in claim 8 were well known at the time of invention. For example, *Salter* discloses the use of a pressure sensor (T) that senses the breathing condition of the user and produces an electrical signal that ultimately controls the flow of oxygen to the user in accordance with the breathing cycle of the user.

28. At the time of invention it would have been obvious to one with ordinary skill in the art to modify the *Sato et al* apparatus to substitute a pressure sensor like the one taught by *Salter* as a known equivalent of the thermocouple to create the invention recited in claim 8.

Additional Pertinent Prior Art

29. The following references are also considered relevant to the applicants' disclosure: US patent nos. 5,626,131, 6,237,594, 4,706,664, 4,686,974 to *Salter*, *Chua et al*, *Davenport*, *Snook et al* and *Sato et al*.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR
June 26, 2003

GLENN K. DAWSON
PRIMARY EXAMINER